

WHAT IS CLAIMED IS:

1. A process of preparing a stable lansoprazole, comprising the steps of:
 - a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of a weak base; and
 - b) isolating a stable lansoprazole.
2. The process of claim 1, wherein the weak base is selected from the group consisting of an ammonium compound and an amine.
3. The process of claim 1, wherein the ammonium compound is selected from the group consisting of ammonia and ammonium hydroxide.
4. The process of claim 1, wherein the amine is selected from the group consisting of diethylamine, triethylamine, diethanolamine, triethanolamine and methylamine.
5. The process of claim 1, wherein the isolating step is performed by precipitating the stable lansoprazole.
6. The process of claim 5, wherein the isolating step includes adding an acid.
7. The process of claim 6, wherein the acid is selected from the group consisting of acetic acid, formic acid and hydrochloric acid.
8. A process of preparing a stable lansoprazole, comprising the steps of:
 - a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water;
 - b) isolating the lansoprazole; and
 - c) drying the lansoprazole in the presence of a weakly basic material to obtain a stable lansoprazole.
9. The process of claim 8, wherein the weakly basic material is selected from the group consisting of an ammonium compound and an amine.
10. The process of claim 9, wherein the ammonium compound is ammonia and the amine is methylamine.
11. The process of claim 8, wherein the isolating step is performed by precipitating the stable lansoprazole.
12. The process of claim 8, wherein the isolating step includes adding an acid.
13. The process of claim 12, wherein the acid is selected from the group consisting of acetic acid, formic acid and hydrochloric acid.
14. The process of claim 8, wherein the weakly basic material in drying step c) is gaseous ammonia.
15. A process of preparing a stable lansoprazole, comprising the steps of:

- a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of a weak base;
 - b) isolating the lansoprazole; and
 - c) drying the lansoprazole in the presence of a weakly basic material to obtain a stable lansoprazole.
16. The process of claim 15, wherein the weak base is selected from the group consisting of an ammonium compound and an amine.
17. The process of claim 16, wherein the ammonium compound is selected from the group consisting of ammonia and ammonium hydroxide.
18. The process of claim 15, wherein the amine is selected from the group consisting of diethylamine, triethylamine, diethanolamine, triethanolamine and methylamine.
19. The process of claim 15, wherein the weakly basic material is selected from the group consisting of an ammonium compound and an amine.
20. The process of claim 19, wherein the ammonium compound is ammonia and the amine is methylamine.
21. The process of claim 19, wherein the weakly basic material is a gas.
22. The process of claim 15, wherein the drying step is performed under vacuum in the presence of an ammonia gas at 45⁰C.
23. The process of claim 15, wherein the isolating step is performed by precipitating the stable lansoprazole.
24. The process of claim 15, wherein the isolating step is performed by adding an acid.
25. The process of claim 24, wherein the acid is acetic acid, formic acid or hydrochloric acid.
26. The process as in one of claims 1, 8 and 15, after step a), further comprises the step of washing the crystallized lansoprazole compound present in a filter cake with an acetone-water mixture in the presence of a weakly basic solution.
27. The process of claim 26, wherein pH of the acetone-water mixture is adjusted to a pH of about 8 to about 10.
28. The process of claim 26, wherein pH of the acetone-water mixture is adjusted to a pH in the range of about 8.5 to about 9.
29. The process as in one of claims 1, 8 and 15, wherein the stable lansoprazole is substantially free of sulfone and sulfide derivatives.
30. The process of claim 29, wherein the stable lansoprazole contains less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative.

31. The process of claim 29, wherein the stable lansoprazole is stable under a storage condition of 2-8⁰C or 25⁰C at a relative humidity of up to 60% for at least about 3 months.
32. The process of claim 29, wherein the stable lansoprazole does not undergo discoloration and remains substantially free of sulfone and sulfide.
33. A stable lansoprazole as prepared by the process of claim 1.
34. A stable lansoprazole as prepared by the process of claim 8.
35. A stable lansoprazole as prepared by the process of claim 15.
36. A pharmaceutical composition comprising a stable lansoprazole of claim 33 and a pharmaceutical acceptable excipient.
37. A pharmaceutical composition comprising a stable lansoprazole of claim 34 and a pharmaceutical acceptable excipient.
38. A pharmaceutical composition comprising a stable lansoprazole of claim 35 and a pharmaceutical acceptable excipient.
39. The process as in one of claims 1, 8 and 15, wherein the organic solvent is selected from the group consisting of ethanol, methanol, n-propanol, i-propanol, acetone, 2-butanone, dimethyl-foramide and tetrahydrofuran.
40. The process of claim 39, wherein the solvent is ethanol.
41. A stable lansoprazole.
42. A lansoprazole containing less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative, upon exposure to a relative humidity of 75% at 40°C for a period of at least about three months.
43. A lansoprazole containing less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative, upon exposure to a relative humidity of 75% at 40°C for a period of at least about six months.
44. A lansoprazole which does not change color upon exposure to a relative humidity of 75% at 40°C for a period of at least about three months.
45. The lansoprazole of claim 44, which does not change color upon exposure to a relative humidity of 75% at 40°C for a period of at least about six months.
46. A process for preparing stable lansoprazole comprising the steps of:
 - a) washing a filter cake comprised of lansoprazole with an ammonium hydroxide solution;

- b) drying the washed lansoprazole in the presence of at least one base selected from the group consisting of ammonia and methyl amine; and
 - c) recrystallizing the dried lansoprazole in the presence of ammonium hydroxide.
- 47. The process of claim 46, wherein the organic solvent is selected from the group consisting of ethanol, methanol, n-propanol, i-propanol, acetone, 2-butanone, dimethyl-formamide and tetrahydrofuran.
- 48. The process of claim 46, wherein the organic solvent is ethanol.
- 49. The process as in one of claims 1, 8 and 15, wherein step a) further comprises heating.
- 50. A process of preparing stable lanzoprazole comprising the step of washing filtered lanzoprazole with a compound selected from the group consisting of amine and ammonium compounds.
- 51. The process of claim 50, wherein the ammonium compound is ammonium hydroxide.
- 52. A process as in one of claims 1, 8 and 15, further comprising the step of washing the filtered lanzoprazole with a compound selected from the group consisting of amine and ammonium compounds.
- 53. The process of claim 52, wherein the ammonium compound is ammonium hydroxide.